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(54) Title: BUFFERED FORMULATIONS FOR CONCENTRATING ANTIBODIES AND METHODS OF USE THEREOF

(57) **Abstract:** The present invention provides a method for producing a concentrated antibody preparation that includes the steps of: (a) obtaining an initial antibody preparation that is an aqueous solution of antibodies and histidine or acetate buffer at a concentration in the range of from about 2 mM to about 48 mM; and (b) subjecting the antibody preparation to membrane filtration so as to remove water and buffer but not antibodies from the antibody preparation, thereby producing an antibody preparation having a higher concentration of antibodies than the initial antibody preparation. The concentrated antibody preparations produced by the method have lower viscosity and are more stable than those of other formulations. The invention further includes concentrated antibody preparations produced by the method, pharmaceutical compositions made using such preparations, and therapeutic methods in which such pharmaceutical compositions are administered to treat diseases.

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US03/19652

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : C07K 16/00; A61K 39/395  
US CL : 530/387.1, 387.3, 388.1; 424/130.1, 133.1, 181.1, 183.1

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 530/387.1, 387.3, 388.1; 424/130.1, 133.1, 181.1, 183.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	WO 03/039485 A2 (KAISHEVA E. A. ET AL) 15 May 2003 (15.06.2003). See entire document.	1-121
A,P	WO 03/009817 A2 (KAISHEVA E. A. ET AL) 06 February 2003 (6.02.2003). See entire document.	1-121
X	WO 02/13860 A1 (MASAYA K. ET AL) 02 February 2002 (02.02.2002). See pages 5-6, 8, and 13.	1-5, 8-11, 14, 18-19
---		6-7, 12-13, 15-17, 20
Y		22
y	US 6,071,519 A (DE BOER ET AL) 06 June 2000 (06.06.2000), columns 2-3, 7, 14-15.	1-22
y	US 6,001,358 A (BLACK ET AL) 14 December 1999 (14.12.1999) columns 6-8.	1-22

Further documents are listed in the continuation of Box C.

See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

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INTERNATIONAL SEARCH REPORT

PCT/US 96

**Continuation of B. FIELDS SEARCHED Item 3:**

WEST, Medline, Biosis, CAPLUS, Inventor name search.

Search terms: antibody, Ig, composition, acetate buffer, histidine buffer, anti-CD20, rituximab, anti-CD80 (IDE-114), anti-gp39, anti-CD23 (IDE-152), anti-CD4 (IDE-151).